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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,961	09/18/2001	Minter H. Dopson	01-2224	8520
27530	7590	10/04/2006	EXAMINER	
NELSON MULLINS RILEY & SCARBOROUGH, LLP 1320 MAIN STREET, 17TH FLOOR COLUMBIA, SC 29201			SCHWADRON, RONALD B	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/954,961

Applicant(s)

DOPSON, MINTER H.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23, 26-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/11/06 has been entered.

2. Claims 23,26-31 are under consideration.

3. The objection to the amendment filed 10/26/05 under 35 U.S.C. 132(a) as per elaborated in the Office Action mailed 4/4/06 (because it introduces new matter into the disclosure 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is the addition of the phrase "incorporated by reference herein in its entirety" in newly added paragraph one, page 1 of the specification. There is no support for said statement in the specification as originally filed.) is withdrawn in view of the amending of the specification to remove the offending subject matter.

4. The rejection of claims 26-31 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons elaborated in the Office Action mailed 4/4/06 are withdrawn in view of the amended claims.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 23,26-28,31 are rejected under 35 U.S.C. 102(b) as being anticipated by Tokoro (US Patent 5,080,895). Applicants arguments have been considered and deemed not persuasive.

Tokoro teaches a method of making transfer factor specific for a pathogen wherein the transfer factor includes the particular transfer factor recited in the claims (because the method of Tokoro uses a filtration step that recovers transfer factor less than 10,000 mw)(see abstract and columns 5-7 and Example II). The specification discloses that transfer factor is less than 10,000 mw (see specification, page 2, last paragraph). The transfer factor is purified from the eggs of an immunized hen (see Example 2). Thus, the transfer factor containing eggs are first collected from the immunized hen. The hens (female birds of the family Phasianidae as per the definition of said term in the specification, page 10, second paragraph) can be immunized with a specific virus to produce an antiviral transfer factor (see column 4, penultimate paragraph). Tokoro discloses that the egg whites (aka albumen) and yolks are mixed with PBS (which contains water), the mixture is treated to remove cell and cell debris (centrifugation) and the supernatant was recovered (see Example II). At least some portion of the fluid would be lost to evaporation. The method uses a preparation that contains "natural egg yolk".

Regarding applicants comments, the method of Tokoro results in a product that contains transfer factor because Tokoro uses a filtration step that recovers transfer factor less than 10,000 mw(see abstract and columns 5-7 and Example II). The specification discloses that transfer factor is less than 10,000 mw (see specification, page 2, last paragraph). *The name used to describe the crude preparation obtained by the method of Tokoro is irrelevant because it contains all molecules less than 10,000 mw, including transfer factor. The method disclosed by Tokoro in Example II discloses steps that the specification discloses would yield a preparation containing transfer factor (centrifugation, filtration and precipitation (see page 14)).* Regarding the Dunnick et al. reference to which applicant refers, as per above the name used to describe the crude preparation obtained by the method of Tokoro is irrelevant because it contains all molecules less than 10,000 mw, including transfer factor. In addition, applicants comments indicate that transfer-like factor cannot transfer immunity. *However, the*

*factor disclosed by Tokoro can transfer immunity (see column 4, first complete paragraph) and therefore appears to be a "transfer factor" (regardless of the name used by Tokoro).* There is no disclosure in the Tokoro patent that their transfer factor has any relation to the molecule disclosed by Dunnick et al. Furthermore, the Dunnick et al. reference does not even disclose that the molecule they have isolated is even found in chickens (it refers to guinea pigs). In addition, the molecule disclosed in Dunnick et al. is prepared using a procedure that is totally different from that used by Tokoro .

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 23,26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (US Patent 5,080,895) in view of Anderson et al. (US Patent 6,475,527).

Applicants arguments have been considered and deemed not persuasive.

Tokoro teaches a method of making transfer factor specific for a pathogen wherein the transfer factor includes the particular transfer factor recited in the claims (because the method of Tokoro uses a filtration step that recovers transfer factor less than 10,000 mw)(see abstract and columns 5-7 and Example II). The specification discloses that transfer factor is less than 10,000 mw (see specification, page 2, last paragraph). The transfer factor is purified from the eggs of an immunized hen (see Example 2). Thus, the transfer factor containing eggs are first collected from the immunized hen. The hens (female birds of the family Phasianidae as per the definition of said term in the specification, page 10, second paragraph) can be immunized with a specific virus to produce an antiviral transfer factor (see column 4, penultimate paragraph). Tokoro discloses that the egg whites (aka albumen) and yolks are mixed with PBS (which contains water), the mixture is treated to remove cell and cell debris (centrifugation) and the supernatant was recovered (see Example II). At least some portion of the fluid would be lost to evaporation. The method uses a preparation that contains "natural egg

yolk". Tokoro does not disclose that the hens receive sodium chlorate. Anderson et al. disclose that fowl can be treated with sodium chlorate to reduce food borne enteric pathogens (see abstract, claim 19, column 2, last paragraph, continued on column 3 and column 3, first complete paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Tokoro teaches the claimed invention except that the hens receive sodium chlorate whilst Anderson et al. disclose that fowl can be treated with sodium chlorate to reduce food borne enteric pathogens (see abstract, claim 19, column 2, last paragraph, continued on column 3 and column 3, first complete paragraph). At least a portion of the administered sodium chlorate would end up in the egg. One of ordinary skill in the art at the time the invention was made would have been motivated to do the aforementioned because Anderson et al. disclose that fowl can be treated with sodium chlorate to reduce food borne enteric pathogens wherein enteric pathogens in animal food products are a problem (column 1, penultimate paragraph).

Applicants arguments are the same as addressed above.

9. No claim is allowed.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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Art Unit 1644